

Congress of the United States
Washington, DC 20515

July 17, 2023

The Honorable Michael S. Regan
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW, Mail Stop 1301A
Washington, DC 20460

Dear Administrator Regan,

We write as Members of Congress who represent—or are otherwise concerned about—communities around the country impacted by dangerous levels of ethylene oxide (EtO) emissions. In 2019, many of us formed the bipartisan U.S. House of Representatives EtO Task Force to advocate for tightening emissions standards for EtO sterilization facilities. In the Senate, we have consistently encouraged the agency to share critical public health information with communities located near EtO facilities, as well as to strengthen public health protections through regulatory action. We all welcome the U.S. Environmental Protection Agency's (EPA) recently proposed Clean Air Act rule strengthening emissions monitoring and control requirements at EtO sterilization facilities, and we appreciate your engagement with the EtO Task Force and other concerned Members as you developed the proposed rule. As many of us have worked on this issue for years and represent impacted communities, we write to provide comments on the proposal.

First, we appreciate EPA implementing many of the EtO Task Force's requests throughout the process of developing the proposed rule. We especially commend EPA for putting public health at the forefront of its considerations by conducting a residual risk review to support the proposal—in line with the May 2021 report by EPA's Office of Inspector General that made the same recommendation. We also appreciate EPA's efforts to engage affected communities as it developed the proposed rule, and we urge EPA to make community engagement a core component of its process as it finalizes and implements the rule. For example, including in the final rule the proposed requirement for sterilizers to obtain a Title V operating permit would ensure that affected communities can comment on compliance.

We recognize that EPA aims to address both fugitive and stack emissions in its proposed rule, both of which have been demonstrated to contribute pollution to our communities. However, we would like to reiterate our position that fugitive emissions cannot be confidently accounted for without a requirement for ambient air monitoring. As we saw in Willowbrook, IL, it was only after ambient air monitoring was conducted that we fully understood the significant role fugitive emissions played in community exposure. Given strong evidence that fence-line monitoring is a proven method for verifying the effectiveness of emission control equipment and detecting fugitive emissions, we encourage you to include requirements for fence-line monitoring in the final rule.

We have also heard concern from our community stakeholders that offsite storage warehouses

are excluded from regulation under the proposed rule. We share the concern that this loophole could create a perverse incentive for industry to use these offsite facilities as secondary aeration rooms for off-gassing EtO-sterilized medical equipment — skirting requirements for health-protective emission controls and monitoring, while failing to provide a clear picture of the extent of EtO being emitted into communities. Warehouse facilities have been a major source of fugitive emissions at EtO sites in Georgia. We must learn from this experience and apply health-protective requirements for all facilities that pose potential exposure to neighboring communities. As such, we ask that you clarify in the final rule whether offsite storage warehouses are covered facilities, and ask that the agency explore all regulatory options for addressing emissions from these facilities.

Communities have been exposed to unmonitored and largely uncontrolled EtO pollution from sterilization facilities for far too long. EPA’s proposed rule, which is slated to become final in March 2024, should come as no surprise to industry stakeholders. EPA’s proposed 18 month compliance timeline beginning in March 2024 provides more than enough time for sterilizers to purchase and install the equipment needed to monitor and control EtO emissions pursuant to the rule. Given the dangerous risk EtO exposure continues to present to communities, we urge EPA to consider adopting a shorter compliance timeline in the final rule.

Thank you again for proposing a rule tightening emissions standards for EtO sterilization facilities. We believe this rule will make significant progress in making public health the touchstone for EtO sterilization facility regulations and reducing dangerous EtO emissions. We also applaud the EPA’s efforts to engage and work with other agencies to fully address the public health implications of EtO emissions. We thank you for considering our comments in our joint effort to reassure communities that the air they breathe is safe. We look forward to working together throughout this process as the rule is finalized and implemented.

Sincerely,



Bradley Scott Schneider
Member of Congress



Richard J. Durbin
United States Senator



Thomas R. Carper
United States Senator



Tammy Duckworth
United States Senator



Steve Cohen
Member of Congress



Bernard Sanders
United States Senator



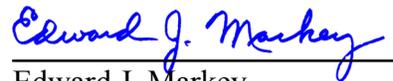
David Scott
Member of Congress



Jeffrey A. Merkley
United States Senator



Henry C. "Hank" Johnson, Jr.
Member of Congress



Edward J. Markey
United States Senator



Sean Casten
Member of Congress



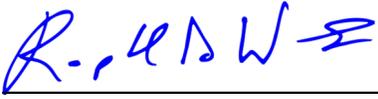
Lauren Underwood
Member of Congress



Troy Carter
Member of Congress



Henry Cuellar
Member of Congress



Raphael Warnock
United States Senator



Chris Van Hollen
United States Senator



Cory A. Booker
United States Senator



John P. Sarbanes
Member of Congress



Diana DeGette
Member of Congress



Jan Schakowsky
Member of Congress



Robin L. Kelly
Member of Congress



Nanette Diaz Barragán
Member of Congress



Jason Crow
Member of Congress



Emanuel Cleaver, II
Member of Congress



Joaquin Castro

Member of Congress



Jennifer L. McClellan

Member of Congress



Robert Garcia

Member of Congress



Mike Quigley

Member of Congress



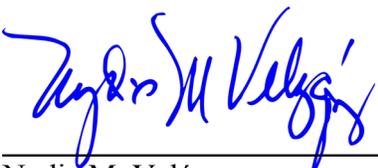
Raja Krishnamoorthi

Member of Congress



Alexandria Ocasio-Cortez

Member of Congress



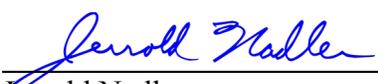
Nydia M. Velázquez

Member of Congress



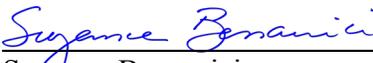
Earl Blumenauer

Member of Congress



Jerrold Nadler

Member of Congress



Suzanne Bonamici

Member of Congress



Colin Z. Allred
Member of Congress



Raúl M. Grijalva
Member of Congress



Sheila Jackson Lee
Member of Congress



Summer Lee
Member of Congress



Jasmine Crockett
Member of Congress



Al Green
Member of Congress